WHAT IS CLAIMED IS

1. A method for sterilizing one or more heart valves that are sensitive to radiation, said method comprising irradiating said one or more heart valves with radiation for a time effective to sterilize said one or more heart valves at a rate effective to sterilize said one or more heart valves and to protect said one or more heart valves from said radiation.

2. A method for sterilizing one or more heart valves that are sensitive to radiation, said method comprising:

(i) applying to said one or more heart valves at least one stabilizing process selected from the group consisting of:

(a) adding to said one or more heart valves at least one stabilizer in an amount effective to protect said one or more heart valves from said radiation;

(b) reducing the residual solvent content of said one or more heart valves to a level effective to protect said one or more heart valves from said radiation;

(c) reducing the temperature of said one or more heart valves to a level effective to protect said one or more heart valves from said radiation;

(d) reducing the oxygen content of said one or more heart valves to a level effective to protect said one or more heart valves from said radiation;

(e) adjusting the pH of said one or more heart valves to a level effective to protect said one or more heart valves from said radiation; and

(f) adding to said one or more heart valves at least one non-aqueous solvent in an amount effective to protect said one or more heart valves from said radiation;

and

(ii) irradiating said one or more heart valves with a suitable radiation at an effective rate for a time effective to sterilize said one or more heart valves.

3. A method for sterilizing one or more heart valves that are sensitive to radiation, said method comprising:

(i) applying to said one or more heart valves at least one stabilizing process selected from the group consisting of:

(a) adding to said one or more heart valves at least one stabilizer;

(b) reducing the residual solvent content of said one or more heart valves;

(c) reducing the temperature of said one or more heart valves;

(d) reducing the oxygen content of said one or more heart valves;

(e) adjusting the pH of said one or more heart valves; and

(f) adding to said one or more heart valves at least one non-aqueous solvent;

and

(ii) irradiating said one or more heart valves with a suitable radiation at an effective rate for a time effective to sterilize said one or more heart valves, wherein said at least one stabilizing process and the rate of irradiation are together effective to protect said one or more heart valves from said radiation.

4. A method for sterilizing one or more heart valves that are sensitive to radiation, said method comprising:

(i) applying to said one or more heart valves at least two stabilizing processes selected from the group consisting of:

(a) adding to said one or more heart valves at least one stabilizer;

(b) reducing the residual solvent content of said one or more heart valves;

(c) reducing the temperature of said one or more heart valves;

(d) reducing the oxygen content of said one or more heart valves;

(e) adjusting the pH of said one or more heart valves; and

(f) adding to said one or more heart valves at least one non-aqueous solvent;

and

(ii) irradiating said one or more heart valves with a suitable radiation at an effective rate for a time effective to sterilize said one or more heart valves, wherein said at least two stabilizing processes are together effective to protect said one or more heart valves from said radiation and further wherein said at least two stabilizing processes may be performed in any order.

5. The method according to claim 2, 3 or 4, wherein said residual solvent is an organic solvent.

6. The method according to claim 1, 2, 3 or 4, wherein said effective rate is not more than about 3.0 kGy/hour.

7. The method according to claim 1, 2, 3 or 4, wherein said effective rate is not more than about 2.0 kGy/hr.

8. The method according to claim 1, 2, 3 or 4, wherein said effective rate is not more than about 1.0 kGy/hr.

9. The method according to claim 1, 2, 3 or 4, wherein said effective rate is not more than about 0.3 kGy/hr.

10. The method according to claim 1, 2, 3 or 4, wherein said effective rate is more than about 3.0 kGy/hour.

11. The method according to claim 1, 2, 3 or 4, wherein said effective rate is at least about 6.0 kGy/hour.

12. The method according to claim 1, 2, 3 or 4, wherein said effective rate is at least about 18.0 kGy/hour.

13. The method according to claim 1, 2, 3 or 4, wherein said effective rate is at least about 30.0 kGy/hour.

14. The method according to claim 1, 2, 3 or 4, wherein said effective rate is at least about 45 kGy/hour.

15. The method according to claim 1, 2, 3 or 4, wherein said one or more heart valves is maintained in a low oxygen atmosphere.

16. The method according to claim 1, 2, 3 or 4, wherein said one or more heart valves is maintained in an atmosphere comprising at least one noble gas or nitrogen.

17. The method according to claim 16, wherein said noble gas is argon.

18. The method according to claim 1, 2, 3 or 4, wherein said one or more heart valves is maintained in a vacuum.

19. The method according to claim 2, 3 or 4, wherein said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, concentration, addition of a second solvent, evaporation, chemical extraction, spray-drying and vitrification.

20. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 15%.

21. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 10%.

22. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 3%.

23. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 2%.

24. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 1%.

25. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 0.5%.

26. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 0.08%.

27. The method according to claim 1, 2, 3 or 4, wherein at least one sensitizer is added to said one or more heart valves prior to said step of irradiating said one or more heart valves.

28. The method according to claim 1, 2, 3, or 4, wherein said one or more heart valves contains at least one biological contaminant or pathogen selected from the group consisting of viruses, bacteria, yeasts, molds, fungi, parasites and prions or similar agents responsible, alone or in combination, for TSEs.

29. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is an antioxidant.

30. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is a free radical scavenger or spin trap.

31. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is a combination stabilizer.

32. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is a ligand.

33. The method according to claim 32, wherein said ligand is heparin.

34. The method according to claim 2, 3 or 4, wherein said at least one stabilizer reduces damage due to reactive oxygen species.

35. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; vitamin E or a derivative thereof, including Trolox; albumin; sucrose; glycylglycine; L-carnosine; cysteine; silymarin; diosmin; hydroquinonesulfonic acid; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; ethanol; acetone; rutin; epicatechin; biacalein; purpurogallin; coumaric acid; and mixtures of two or more thereof.

36. The method according to claim 35, wherein said mixtures of two or more stabilizers are selected from the group consisting of: mixtures of ethanol and acetone; mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof, and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof, and cysteine; mixtures of ascorbic acid, or a salt or ester thereof, and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic

acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid; mixtures of Trolox, α-lipoic acid, coumaric acid and n-propyl gallate;and mixtures of uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate, gallic acid, or a derivative thereof, propyl gallate, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

37. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is a dipeptide stabilizer.

38. The method according to claim 37, wherein said dipeptide stabilizer is selected from the group consisting of glycyl-glycine (Gly-Gly), carnosine and anserine.

39. The method according to claim 1, 2, 3 or 4, wherein said radiation is corpuscular radiation, electromagnetic radiation, or a mixture thereof.

40. The method according to claim 39, wherein said electromagnetic radiation is selected from the group consisting of radio waves, microwaves, visible and invisible light, ultraviolet light, x-ray radiation, gamma radiation and combinations thereof.

41. The method according to claim 1, 2, 3 or 4, wherein said radiation is gamma radiation.

42. The method according to claim 1, 2, 3 or 4, wherein said radiation is E-beam radiation.

43. The method according to claim 1, 2, 3 or 4, wherein said radiation is visible light.

44. The method according to claim 1, 2, 3 or 4, wherein said radiation is ultraviolet light.

45. The method according to claim 1, 2, 3 or 4, wherein said radiation is x-ray radiation.

46. The method according to claim 1, 2, 3 or 4, wherein said radiation is polychromatic visible light.

47. The method according to claim 1, 2, 3 or 4, wherein said radiation is infrared.

48. The method according to claim 1, 2, 3 or 4, wherein said radiation is a combination of one or more wavelengths of visible and ultraviolet light.

49. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted at ambient temperature.

50. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted at a temperature below ambient temperature.

51. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted below the freezing point of at least one or more solvents within or surrounding said one or more heart valves.

52. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted below the eutectic point of at least one or more solvents within or surrounding said one or more heart valves.

53. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted at a temperature above ambient temperature.

54. A composition comprising one or more heart valves and at least one stabilizer in an amount effective to preserve said one or more heart valves for their intended use following sterilization with radiation.

55. A composition comprising one or more heart valves, wherein the residual solvent content of said one or more heart valves is at a level effective to preserve said one or more heart valves for their intended use following sterilization with radiation.

56. The composition of claim 55, wherein said residual solvent content is less than about 15%.

57. The composition of claim 55, wherein said residual solvent content is less than about 10%.

58. The composition of claim 55, wherein said residual solvent content is less than about 5%.

59. The composition of claim 55, wherein said residual solvent content is less than about 2%.

60. The composition of claim 55, wherein said residual solvent content is less than about 1%.

61. The composition of claim 55, wherein said residual solvent content is less than about 0.5%.

62. The composition of claim 55, wherein said residual solvent content is less than about 0.08%.

63. The composition of claim 54 or 55, wherein said one or more heart valves is glassy or vitrified.

64. The method according to claim 2, 3 or 4, wherein said non-aqueous solvent is selected from the group consisting of glycerol, DMSO, ethanol, acetone, PPG, and mixtures thereof.

65. The method according to claim 64, wherein said PPG is PPG 400, PPG 1200 or PPG 2000.

66. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 0%.

67. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 1%.

68. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 2.4%.

69. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 4.8%.

70. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 7%.

71. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 9%.

72. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 10%.

73. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 20%.

74. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 33%.

75. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 33%.

76. The composition of claim 54, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; vitamin E or a derivative thereof; albumin; Trolox; coumaric acid; sucrose; glycylglycine; L-carnosine; cysteine; silymarin; diosmin; hydroquinonesulfonic acid; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; ethanol; acetone; rutin; epicatechin; biacalein; purpurogallin; and mixtures of two or more thereof.

77. The composition according to claim 76, wherein said mixtures of two or more stabilizers are selected from the group consisting of: mixtures of ethanol and acetone; mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic

acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof, and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof, and cysteine; mixtures of ascorbic acid, or a salt or ester thereof, and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid; mixtures of Trolox, α-lipoic acid, and coumaric acid; mixtures of Trolox, α-lipoic acid, coumaric acid and n-propyl gallate; and mixtures of uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate, gallic acid, or a derivative thereof, propyl gallate, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

78. A method for prophylaxis or treatment of a condition or disease in a mammal comprising introducing into a mammal in need thereof one or more heart valves stabilized according to a method of one of claims 1, 2, 3 or 4.

79. The method according to claim 2, 3 or 4, wherein said residual solvent is an aqueous solvent.

80. The method according to claim 2, 3 or 4, wherein said one or more heart valves is suspended in said solvent.

81. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted below the glass transition point of at least one or more solvents within or surrounding said one or more heart valves.

82. The method according to claim 1, 2, 3 or 4, wherein the recovery of the desired characteristic(s) or composition of the one or more heart valves after sterilization by irradiation is greater than 100% of the pre-irradiation value.

83. The method according to claim 1, 2, 3 or 4, wherein the recovery of the desired characteristic(s) or composition of the one or more heart valves after sterilization by irradiation is at least about 100% of the pre-irradiation value.

84. The method according to claim 1, 2, 3, 4 or 11, wherein the recovery of the desired activity of the one or more heart valves after sterilization by irradiation is at least about 90% of the pre-irradiation value.

85. The method according to claim 1, 2, 3, 4 or 11, wherein the recovery of the desired activity of the one or more heart valves after sterilization by irradiation is at least about 80% of the pre-irradiation value.

86. The method according to claim 1, 2, 3, 4 or 11, wherein the recovery of the desired activity of the one or more heart valves after sterilization by irradiation is at least about 70% of the pre-irradiation value.

87. The method according to claim 1, 2, 3, 4 or 11, wherein the recovery of the desired activity of the one or more heart valves after sterilization by irradiation is at least about 60% of the pre-irradiation value.

88. The method according to claim 1, 2, 3, 4 or 11, wherein the recovery of the desired activity of the one or more heart valves after sterilization by irradiation is at least about 50% of the pre-irradiation value.

89. One or more heart valves prepared according to a method of one of claims 1, 2, 3 or 4.

90. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 80%.

91. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 50%.

92. The composition of claim 55, wherein said residual solvent content is less than about 80%.

93. The composition of claim 55, wherein said residual solvent content is less than about 50%.

94. A composition comprising one or more heart valves, at least one non-aqueous solvent and at least one stabilizer in an amount effective to preserve said one or more heart valves for their intended use following sterilization with radiation.

95. The composition of claim 94, wherein said at least one non-aqueous solvent comprises DMSO and said at least one stabilizer comprises ascorbate.

96. The composition of claim 94, wherein said at least one non-aqueous solvent comprises DMSO and said at least one stabilizer comprises a mixture of ascorbate, coumaric acid and n-propyl gallate.

97. The composition of claim 94, wherein said at least one non-aqueous solvent comprises PPG and said at least one stabilizer comprises ascorbate.

98. The method according to claim 4, wherein, said at least two stabilizing processes comprise:

a. adding to said one or more heart valves at least one stabilizer; and
b. adding to said one or more heart valves at least one non-aqueous solvent.

99. The method according to claim 98, wherein said at least one non-aqueous solvent comprises DMSO and said at least one stabilizer comprises ascorbate.

100. The method according to claim 98, wherein said at least one non-aqueous solvent comprises DMSO and said at least one stabilizer comprises a mixture of ascorbate, coumaric acid and n-propyl gallate.

101. The method according to claim 98, wherein said at least one non-aqueous solvent comprises PPG and said at least one stabilizer comprises ascorbate.

102. The method according to claim 2, 3 or 4, wherein the residual solvent is a mixture of an organic solvent and an aqueous solvent.

103. A composition comprising one or more heart valves and at least one stabilizer, wherein the residual solvent content of said one or more heart valves is at a level that together with said at least one stabilizer is effective to preserve said one or more heart valves for their intended use following sterilization with radiation.

104. The composition according to claim 54, 55 or 103, wherein the oxygen content of said one or more heart valves is reduced to a level that together with said at least one stabilizer and/or said residual solvent content is effective to protect said one or more heart valves from sterilization with radiation.